ATTACHMENT #5
Dibutyl Sebacate

Part IV — Environmental Impact of Food Contact Substance (21 CFR part 25)

B. Environmental Assessment

This environmental assessment has been prepared in accordance with 21 CFR 25.31a, using the abbreviated format described in (b)(1).

1) Date: October 3, 2003

2) Name of notifier: Ciba Specialty Chemicals Corporation

3) Address: 540 White Plains Road
Tarrytown, NY 10591

4) Description of the proposed action:

Requested action:
It is proposed that the use of dibutyl sebacate (DBS), CASRN 109-43-3, as a dispersing agent for colorants, at a maximum concentration of 0.015%, by weight in the finished article, for use in all polymers for food contact applications.

Need for action:
The dibutyl sebacate will be used as a dispersing agent for colorants for use in molded articles.

Location of use:
The FCS is manufactured in Germany. The material could possibly be used at various colorant production facilities including ones located in Germany and the United States. The FCS is expected to be widely distributed across the United States in patterns corresponding to national population density.

Location of disposal:
The food contact substance (FCS) is used at the colorant production facilities. During colorant production, a scrubber captures the FCS that is lost during the spray-drying step of the process. Then the wastewater in the scrubber goes directly to a wastewater treatment plant, where the FCS is biologically degraded.

5) Identification of the chemical substances that are the subject of the proposed action:

CAS Name:
Dibutyl Sebacate

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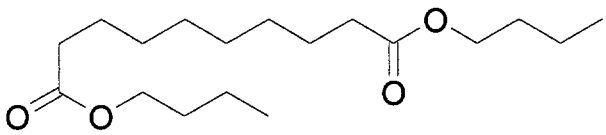
Dibutyl Sebacate
CAS Registry Number:
109-43-3



$C_{18}H_{34}O_4$
Molecular Weight 314.46

Physical description:
Liquid

6) Introduction of substances into the environment:

a) Introduction of substances into the environment as a result of manufacture:
This product will be manufactured in Germany. No extraordinary circumstances apply to the manufacture of the FCS.

b) Introduction of substances into the environment as a result of use:
Little or no introduction of dibutyl sebacate will result from its use. The dibutyl sebacate is added at 10% during its use, as a dispersing agent for pigments, and up to 70% is lost during the spray-drying process. However, since this material is captured by the scrubber, it will not be introduced into the environment.

The dibutyl sebacate is then present in colorants, as a residual component at <3.0 wt-%. The residual amount of dibutyl sebacate expected in a molded article, based on a colorant loading of 0.5% would be 0.015 wt-%. The colorant is completely incorporated into a finished article and essentially all of it, as well as dibutyl sebacate, is expected to remain with the molded articles throughout their lifetime.

c) Introduction of substances into the environment as a result of disposal:
i) Landfills:
Only very low levels of the FCS which would be incorporated into molded polymer articles, are expected to leach from these materials in landfills. Moreover, even if a very small amount of the FCS migrates from the food packaging in landfills, we expect extremely low quantities to actually enter the environment; this finding is based on the Environmental Protection Agency's (EPA's) regulations governing municipal solid waste landfills. In addition, introducing these substances into the environment will not threaten a violation of the Environmental Protection Agency's (EPA) regulations in 40 CFR part 258 that pertain to landfills.
ii) Combustion:
The dibutyl sebacate is composed of carbon, hydrogen, and oxygen, elements commonly found in municipal solid waste. The complete combustion of this FCS in a properly functioning incinerator will produce only carbon dioxide and water. Because the market volume of the FCS is a small fraction of the municipal solid waste generated and

disposed in the United States, adding the FCS to waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the nature of the combustion products and their low levels compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion products from incineration of the molded articles containing the will cause a violation of applicable emissions laws and regulations.

7) Fate of substances released into the environment:

No information need be provided on the fate of substances released into the environment as the result of use and disposal of, because only small quantities of substances, if any, will be introduced into the environment from its use and disposal. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR parts 60 and 258.

8) Environmental effects of released substances:

No information need be provided on the environmental effects of the substances released into the environment as a result of use and/or disposal of dibutyl sebacate because only small quantities, if any, of the substances will be introduced into the environment as a result of the use and disposal of this product. Therefore, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR parts 60 and 258.

9) Use of resources and energy

Dibutyl sebacate is used as a dispersing agent in the production processes of colorants. During colorant production, no additional resources or energy are required as a result of either the introduction or the removal of dibutyl sebacate in the process.

10) Mitigation measures:

We identify no adverse environmental effects, based upon our review of adequate and complete data and information.

11) Alternatives to the proposed action:

We identify no adverse environmental effects, based upon our review of adequate and complete data and information.

12) List of Preparer :

Naeem Mady
Head, Regulatory Affairs
Ciba Specialty Chemicals Corporation

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Dibutyl Sebacate
13) Certification:

The undersigned certifies that the information presented is true, accurate and complete to the best of the knowledge of Ciba Specialty Chemicals Corporation.

October 3, 2003

Naeem Mady
Head, Regulatory Affairs
Ciba Specialty Chemicals